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(71) Applicant *(for all designated States except US)*: **NEURIM PHARMACEUTICALS (1991) LTD.** [IL/IL]; 8 Hanechoshet Street, 69710 Tel Aviv (IL).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ZISAPEL, Nava** [IL/IL]; 23 Kisufim Street, 69355 Tel Aviv (IL). **LAUDON, Moshe** [IL/IL]; 30 Herzl Street, 44444 Kfar Saba (IL).

(74) Agent: **JEREMY M. BEN-DAVID & CO. LTD.**; P.O. Box 45087, Har Hotzvim Hi-Tech Park, 91450 Jerusalem (IL).

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(54) Title: COMPOSITION FOR IMPROVING COGNITION AND MEMORY

(57) Abstract: The invention relates to a pharmacologically active combination, having utility in treating insomnia patients, which comprises: (a) at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and (b) at least one second active ingredient selected from nicotine and nicotine receptor agonists; to use of a medicament containing component (a) with or without component (b) for alleviation of at least one adverse effect which occurs in a patient in the course of nicotine replacement therapy, or otherwise, selected from impairment of the quality of sleep, impairment of cognition and impairment of memory, as well as to a kit having utility in treating insomnia patients, which comprises components (a) and (b) in unit dosage form.

WO 2004/096118 A3

AMENDED CLAIMS

[Received by the International Bureau on 21 September 2005 (21.09.2005) ; original claims 6 and 11, amended; remaining claims, unchanged]

1. A pharmacologically active combination, having utility in treating insomnia patients, which comprises:
(a) at least one first active ingredient selected from melatonin, other *melatonergic agents, melatonin agonists and melatonin antagonists; and*
(b) at least one second active ingredient selected from nicotine and nicotine receptor agonists.

2. A pharmacologically active combination according to claim 1, which is characterized by at least one of the following features:
(i) it comprises also at least one diluent, carrier or adjuvant;
(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;
(iii) it is a controlled, sustained or prolonged release formulation;
(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;
(v) said ingredient (a) is melatonin;
(vi) said ingredient (b) is nicotine;
(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;
(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

3. A pharmacologically active combination according to claim 2, which is in said form of dosage units, wherein each dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

4. A pharmacologically active combination according to claim 3, wherein said amount lies within the range of 0.25 to 50 mg.

5. A pharmacologically active combination according to claim 4, wherein said amount lies within the range of 0.5 to 40 mg.

6. Use of at least one first active ingredient (a) selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, in the manufacture of a first medicament for treating a patient in the course of nicotine replacement therapy, for the purpose of alleviating at least one of the following adverse effects which occur in the patient, namely, impairment of the quality of sleep, impairment of cognition and impairment of memory, wherein the patient may optionally be receiving simultaneously a second medicament comprising at least one second active ingredient (b) selected from nicotine and nicotine receptor agonists.

7. Use according to claim 6, wherein each of said medicaments is characterized respectively by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

8. Use according to claim 7, wherein said first and second medicaments are respectively in said form of dosage units, wherein each said dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

9. Use according to claim 8, wherein said amount lies within the range of 0.25 to 50 mg.

10. Use according to claim 9, wherein said amount lies within the range of 0.5 to 40 mg.

11. Use of at least one first active ingredient (a) selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, in the manufacture of a first medicament for treating a patient not in the course of nicotine replacement therapy, for the purpose of alleviating at least one of the following adverse effects which occur in the patient, namely, impairment of the quality of sleep, impairment of cognition and impairment of memory, wherein the patient is one receiving simultaneously a second medicament comprising at least one second active ingredient (b) selected from nicotine and nicotine receptor agonists.

12. Use according to claim 11, wherein each of said medicaments is characterized respectively by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period; (v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

13. Use according to claim 12, wherein said first and second medicaments are respectively in said form of dosage units, wherein each said dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

14. Use according to claim 13, wherein said amount lies within the range of 0.25 to 50 mg.

15. Use according to claim 14, wherein said amount lies within the range of 0.5 to 40 mg.

16. A kit having utility in treating insomnia patients, which comprises:
(A) a first pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and
(B) a second pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one second active ingredient selected from nicotine and nicotine receptor agonists;
wherein the dosage units in (A) and (B) are independently selected from those adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration.

17. A kit according to claim 16, which is further characterized by at least one of the following features:
(α) at least one of (A) and (B) is a controlled, sustained or prolonged release formulation;
(β) at least one of (A) and (B) is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;
(γ) said at least one first active ingredient comprises melatonin;
(δ) said at least one second active ingredient comprises nicotine;
(ε) (A) comprises also at least one melatonin receptor modifier and/or melatonin profile modifier;
(ζ) (A) comprises also at least one further active ingredient selected from nicotine and nicotine receptor agonists;
(η) said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.025-100 mg.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61K 43/64; 31/405
US CL : 514/343, 415
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 514/343, 415

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,353,015 B1 (OXENKRUG et al) 05 March 2002 (05.03.2002), column 12, lines 20-25).	1-21
Y	US 6,486,172 B2 (MYERS et al.) 26 November 2002 (26.11.2002) column 17, lines 30-34.	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
Sreenivasan Padmanabhan
Telephone No. 703-308-1235

Janice Ford
for

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